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TITLE: Evaluation of Spine Health and Spine Mechanics in Servicemembers with Traumatic Lower Extremity Amputation or Injury

PRINCIPAL INVESTIGATOR: Bradford D. Hendershot, PhD

RECIPIENT: Henry M. Jackson Foundation, for the Advancement of Military Medicine
Bethesda, MD 20817

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
Low back pain (LBP) is a clinically important secondary impairment following lower-extremity trauma, with an estimated prevalence as high as 52-80%. During gait, alterations in trunk motion following lower limb amputation likely impose distinct demands on trunk muscles to maintain equilibrium and stability of the spine. The overall objective of this research is to identify the relationship(s) between trunk motion with traumatic lower-extremity amputation/injury and LBP via changes in spine mechanics and spine health, two important factors associated with LBP risk. Using a novel set of clinical, experimental, and computational methods, we expect to demonstrate a positive association between abnormal spine mechanics (i.e., increased spinal loads), that overtime, negatively affect spine health and increase LBP risk among SMs with lower-extremity trauma. Preliminary results, to date, support our working hypothesis that altered trunk motions with extremity trauma contribute to increase spinal loads by 17-95% relative to able-bodied individuals. Experimental methods are operational and enrollment is currently open (9 participants recruited) to obtain additional prospective data. We expect to show a positive association between elevated spine loads and poor spine health, which will support the need for trunk-specific rehabilitation procedures to reduce long-term incidence and recurrence of low back pain.

15. SUBJECT TERMS
Low Back Pain; Intervertebral Disc; Inter-Segmental Motion; Spine Load; Spinal Alignment; Fluoroscopy; Finite Element Model

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Linking lower-extremity amputation/injury with low back pain (LBP) risk via biomechanical theory suggests that altered and asymmetric trunk kinematics and corresponding passive spinal tissue and trunk neuromuscular responses alter spine mechanics such that would, over time, adversely affect spine health. Therefore, the overall objective of this study is to investigate such relationships through cross-sectional evaluations of spine health and spine mechanics in persons with lower-extremity amputation/injury (with and without LBP) and uninjured controls.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Low Back Pain; Intervertebral Disc; Inter-Segmental Motion; Spine Load; Spinal Alignment; Fluoroscopy; Finite Element Model

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Specific Aim 1: Quantify lumbar spinal alignment and inter-segmental vertebral motions with traumatic lower-extremity amputation.

Major Task 1: Obtain IRB and HRPO approvals.

Target Date: by April 2015

Actual Date: April 24, 2015 (IRB approval) / June 26, 2015 (HRPO approval)

Major Task 2: Complete biomechanical data collections, analysis, and interpretations.

Target Dates: Months 6-24 (10% complete)

Additional Milestones: Two abstracts (1 presented) and two manuscripts submitted (1 submitted) to relevant conferences and archival journals.

Specific Aim 2: Quantify alterations in spine mechanics (loading) with traumatic lower-extremity amputation.

Major Task 3: Estimate spinal loads using collected biomechanical data as inputs into the finite element model of the lumbar spine.

Target Dates: Months 6-24 (0% complete)

Additional Milestones: One abstract and one manuscript submitted to relevant conference and archival journal.

Specific Aim 3: Determine associations between spine loading and current spine health with traumatic lower-extremity amputation.

Major Task 4: Conduct physical spinal examinations.

Target Dates: Months 6-24 (0% complete)

Major Task 5: Obtain magnetic resonance images of the lumbar spine for quantitative evaluation of lumbar disc health.

Target Dates: Months 6-24 (0% complete)

Major Task 6: Author manuscript on entire study.

Target Dates: Months 30-36 (0% complete)

Additional Milestones: One abstract and two manuscripts submitted to relevant conference and archival journal.

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

During the first year of this award, all work was performed under major task 1. This mainly included the preparation and submission of all documents required for local IRB review. Specifically, this project was submitted for departmental scientific review (a required local precursor to IRB submission) on October 3, 2014, approved on December 2, and subsequently submitted to the IRB on December 3. Following administrative review, the project tabled at the full IRB meeting on February 26, 2015, during which I presented and defended the project. I was granted "conditional" approval, pending minor modifications. A formal letter outlining the requested changes was provided to me on March 24, 2015. I immediately responded with updated files to the requested changes, and the package was forwarded to the IRB for final approval on March 27, 2015. Official IRB approval was conveyed on April 1, formal approval documents were uploaded to IRBnet on April 24, and all HRPO documents were submitted for HRPO review on April 28. During HRPO review, it was determined that the University of Kentucky required additional HRPO approval for the work being performed under their subaward. HRPO approval for WRNMMC was granted on June 26 (A-18549.1), and approval for University Kentucky was approved on June 29 (A-18549.2). Walter Reed IRB start date (i.e., approval to begin study) given on August 5, 2015.

Additional testing was conducted to ensure feasibility of experimental methods, and a site visit was conducted on April 24 among all investigators. Using preliminary data while waiting for approvals, we also presented 1 abstract at the 7th World Congress of Biomechanics and submitted 1 manuscript (currently under review) to Clinical Biomechanics, both supporting Major Tasks 1 and 3 (see Appendix).

Nine participants (at WRNMMC) have been recruited for the data collection phase. Note, all recruitment and data collections take place at WRNMMC.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Under the subaward to the University of Kentucky, Dr. Bazrgari and I are providing mentorship to a PhD student (Iman Shojaei). Beyond that, the project was not necessarily intended to provide training or professional development opportunities.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

To date, only preliminary results are available; however, these were disseminated at the 7th World Congress of Biomechanics as a podium presentation to an international audience of biomechanics experts. A full manuscript was also prepared and is currently under review for publication in the journal of Clinical Biomechanics. Additional avenues of dissemination will be pursued as new data is collected in Year 2 of this award.

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Having completed the lengthy IRB approval process here at Walter Reed, we are now ready to begin data collections in support of Major Tasks 2, 3, 4, and 5 (conducted in parallel). The second year of this award will be critical as we begin these data collections.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Preliminary data (see Appendix) supports our working hypothesis that altered trunk motion with lower extremity trauma contributes to increase loads within the spine. Briefly, Trunk muscle force and spinal load maxima corresponded with heel strike and toe-off events, and were respectively 10-40% and 17-95% larger during intact vs. prosthetic stance in persons with amputation, as well as 6-80% and 26-60% larger during intact stance relative to controls. A critical next step is understanding the relationship between these elevated spinal loads with current spine health. Depending on this, we expect to make a significant impact on clinical care with regard to trunk specific rehabilitation interventions.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The only delays during this reporting period are related to IRB and associated (HRPO) approvals. While we expected this to be a lengthy process (~6 months), there were several minor hiccups along the way that, in total, significantly increased the approval time. In particular, scientific review, radiation review, and recent changes in overall IRB submission procedures delayed our project start date. Knowing these challenges, we delayed the hiring process for the Research Assistant by several months; the job is currently posted and interviewing underway. As these were one-time events, there is no need/plan to resolve them.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

As noted above, delays in IRB/HRPO approvals delayed the hiring process for the Research Assistant. As such, personnel expenditures YTD were below what was originally budgeted.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

No significant changes to report. As noted above, IRB/HRPO approval dates: IRB approval granted on April 1, 2015 (formal approval documents were uploaded to IRBnet on April 24) HRPO approval for WRNMMC was granted on June 26, 2015 (A-18549.1) HRPO approval for University Kentucky was granted on June 29, 2015 (A-18549.2) Walter Reed IRB official start date (permission to begin study): August 4, 2015

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Shojaei, I., **Hendershot, B.D.**, Wolf, E.J., and Bazrgari, B. Increased and Asymmetric Trunk Motions during Level-Ground Walking are Associated with Larger Spinal Loads in Persons with Unilateral Transfemoral Amputation. *Clinical Biomechanics*, Under Review (revisions submitted August 13, 2015). Federal Support acknowledged.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation);*

status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to report.

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

***Hendershot, B.D.**, Wolf, E.J., and Bazrgari, B. (2014) Changes in Gait following Transfemoral Amputation Increase Spinal Loads. *7th World Congress of Biomechanics*, Boston, MA, USA.

Though not directly supported by this award, Dr. Bazrgari also published a methods-based paper when preparing and validating his spine model for the data we are collecting in this project:

Shojaei, I, Arjmand, N, and Bazrgari, B. (2015) An optimization-based method for prediction of lumbar spine segmental kinematics from measurements of thorax and pelvic kinematics. *International Journal of Numerical Methods in Biomedical Engineering* e02729.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research

performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *biospecimen collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award).*

Name:	Bradford Hendershot, PhD
Project Role:	PI
Researcher ID:	NA
Nearest person month worked:	1
Contribution to Project:	Completed/submitted documentation for regulatory review and approval. Co-authored a manuscript with Dr. Bazrgari as mentioned below.
Name:	Babak Bazrgari, PhD
Project Role:	Co-I (PI of Kentucky subaward)
Researcher ID:	NA
Nearest person month worked:	1
Contribution to Project:	Adapted existing finite element model for its application to walking data (with the assistance of his PhD student), as well as co-authored a manuscript related to the estimation of spinal loads among persons with transfemoral amputation during gait. Dr. Bazrgari also visited on April 24, 2015.
Name:	Scott Tashman, PhD
Project Role:	Co-I (PI of Pittsburgh subaward)
Researcher ID:	NA
Nearest person month worked:	1
Contribution to Project:	Completed a site visit on April 24, 2015 to discuss methodology in preparation for data collection. Assisted with calculations related to radiation dose estimates for IRB and HRPO documentation.

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Journal Article(s):

Shojaei, I., **Hendershot, B.D.**, Wolf, E.J., and Bazrgari, B. Increased and Asymmetric Trunk Motions during Level-Ground Walking are Associated with Larger Spinal Loads in Persons with Unilateral Transfemoral Amputation. *Clinical Biomechanics*, Under Review (revisions submitted August 13, 2015). Federal Support acknowledged.

Abstract(s):

Hendershot, B.D., Wolf, E.J., and Bazrgari, B. (2014) Changes in Gait following Transfemoral Amputation Increase Spinal Loads. *7th World Congress of Biomechanics*, Boston, MA, USA.

Increased and asymmetric trunk motion during level-ground walking is associated with larger spinal loads in persons with unilateral transfemoral amputation

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Number of Tables: 3

ABSTRACT

Background: During gait, alterations in trunk motion following lower limb amputation likely impose distinct demands on trunk muscles to maintain equilibrium and stability of the spine. However, trunk muscle responses to such changes in physical demands, and the resultant effects on spinal loads, have yet to be determined in this population.

Methods: Trunk and pelvic kinematics collected during level-ground walking from 40 males (20 with unilateral transfemoral amputation and 20 matched controls) were used as inputs to a kinematics-driven, nonlinear finite element model of the lower back to estimate forces in 10 global (attached to thorax) and 46 local (attached to lumbar vertebrae) trunk muscles, as well as compression, lateral, and antero-posterior shear forces at all spinal levels.

Findings: Trunk muscle force and spinal load maxima corresponded with heel strike and toe-off events, and were respectively 10-40% and 17-95% larger during intact vs. prosthetic stance in persons with amputation, as well as 6-80% and 26-60% larger during intact stance relative to controls.

Interpretation: In addition to larger individual muscle responses to overall increases and asymmetries in trunk motion during walking, co-activations of antagonistic muscles were needed to assure spine equilibrium in three-dimensional space, hence resulting in substantial increases in spinal loads. Knowledge of trunk neuromuscular adaptations to changes in task demands following amputation could inform rehabilitation procedures such to reduce long-term incidence or recurrence of low back pain.

Keywords: Amputation, Gait, Muscle forces, Spinal loads, Low back pain

HIGHLIGHTS:

- Persons with lower limb amputation walk with large and asymmetric trunk motion
- Spinal equilibrium and stability under such motions require large muscular response
- Larger trunk muscle forces contribute to increase compression and shear loads
- Repeated exposures to altered spinal loading may elevate low back pain risk

1. INTRODUCTION

The prevalence of low back pain (LBP) is considerably higher in persons with lower limb amputation (LLA) compared with able-bodied individuals (Friberg, 1984, Sherman, 1989, Sherman et al., 1997, Smith et al., 1999). As a secondary health-related concern, LBP is suggested to be the most important condition that adversely affects the physical performance and quality of life in persons with LLA (Ehde et al., 2001, Taghipour et al., 2009). Providing the projected increase in the number of people with LLA, it is important to investigate the underlying mechanism(s) responsible for the elevated prevalence of LBP in this cohort (Reiber et al., 2010, Devan et al., 2014).

Considering spine biomechanics, spinal loads are the resultant of interactions between internal tissue forces (primarily from muscles) and physical demands of a given activity on the lower back (Cholewicki and Mcgill, 1996, Calisse et al., 1999, Arjmand and Shirazi-Adl, 2005, Adams et al., 2007, Mcgill et al., 2014). During gait, increased and asymmetric trunk motion following LLA has been reported to impose higher physical demands on the lower back (Cappozzo and Gazzani, 1982, Hendershot and Wolf, 2014). Such an increase in physical demand of a common daily activity like walking would require larger responses from internal trunk tissues to assure equilibrium and stability of the spine, hence leading to larger spinal loads that would presumably increase the risk for LBP due to the repetitive nature of such activities (Adams et al., 2007).

There is limited information in the literature related to internal trunk tissue responses and resultant spinal loads during walking (Cappozzo et al., 1982, Cappozzo, 1983, Cappozzo, 1983, Khoo et al., 1995, Cheng et al., 1998, Callaghan et al., 1999, Yoder et al., 2015). All but two of these few earlier studies included relatively small sample sizes of able-bodied male participants and have reported spinal loads at either the L4-L5 or L5-S1 discs. The predicted pattern of spinal loads in these studies included symmetric local maxima occurring around heel strike and toe off within the gait cycle, with values ranging between 1.2 to 3.0 times body weight. The other two studies regarding internal tissue responses and resultant spinal loads during walking also include persons with LLA (Cappozzo and Gazzani, 1982, Yoder et al., 2015). Using kinematics data obtained from two subjects (one with transfemoral amputation and one with knee ankylosis), Cappozzo and Gazzani (1982) used a rigid link-segment model of the whole body to obtain mechanical demands of walking on the lower back. A simple muscle model was then used to calculate internal tissue responses and the resultant spinal loads. Contrary to the patterns of spinal loads observed in able-bodied individuals, the occurrence of local maxima among persons with LLA did not have a symmetric pattern. Rather, the maximum compression forces were larger at the instance of prosthetic vs. intact toe off (2-3.0 vs. 1.0 times body weight). Similar differences in patterns of trunk muscular responses during walking, and the resultant effect on spinal loads (but at much lower magnitudes), between persons with and without transtibial LLA have been recently reported by Yoder et al. (2015). Although these earlier studies highlight the impact of altered and asymmetric gait on loads experienced in the lower back, they were limited to small samples and/or a very simple biomechanical model of the lower back.

Using a relatively large sample size, along with a biomechanical model of the lower back with more bio-fidelity, the objective of this study was to investigate the differences in internal tissue responses, specifically muscle forces, and resultant spinal loads during level-ground walking between individuals with (n=20) and without (n=20) unilateral LLA. Considering that alterations in trunk motion following amputation impose higher (and asymmetric) physical demands on the lower back (Cappozzo and Gazzani, 1982, Hendershot and Wolf, 2014), it was hypothesized that compared to able-bodied individuals, persons with LLA will require larger muscle forces in the lower back to overcome the physical demands of walking while maintaining spinal stability and equilibrium. Such increases in trunk muscle forces would, in turn, result in larger spinal loads. A better knowledge of lower back biomechanics (i.e., in terms of spinal loads) among individuals with LLA can inform future development of effective clinical programs aimed at modifying lower back biomechanics such to mitigate LBP risk.

2. METHODS

2.1 Experimental study: Kinematic data collected in an earlier study were used in these analyses (Hendershot and Wolf, 2014). Briefly, full-body kinematics from 20 males with transfemoral amputation and 20 male able-bodied controls were collected using a 23-camera motion capture system during level-ground walking across a 15 m level walkway at a selfselected speed (mean ≈ 1.35 m/s; Table-1). Here, kinematic data of interest included three-dimensional pelvic and thorax motions that were collected by tracking markers positioned in the mid-sagittal plane over the S1, T10, and C7 spinous processes, sternal notch, and xiphoid; and bilaterally over the acromion, ASIS, and PSIS. All amputations were a consequence of traumatic injuries with a mean (standard deviation) duration of 3.1 (1.4) years since amputation. Main inclusion criteria were: (1) unilateral transfemoral amputation with no contralateral functional impairments, (2) daily use of a prosthetic device (≥1 year post-amputation), (3) no use of an upper-extremity assistive device (e.g., cane, crutches, walker), and (4) having no other musculoskeletal or neurologic problem, except amputation, that may affect gait results. Details of inclusion and exclusion criteria and other experimental methodology can be found in Hendershot and Wolf (2014). This retrospective study was approved by Institutional Review Boards of both University of Kentucky and Walter Reed National Military Medical Center.

Table-1 may be inserted here

2.2 Modeling study: The biomechanical model used to estimate trunk muscle responses and resultant spinal loads included a non-linear finite element (FE) model of the spine that estimated the required muscle forces to complete the activity using an optimization-based iterative procedure (Arjmand and Shirazi-Adl, 2005, Arjmand and Shirazi-Adl, 2006, Bazrgari et al., 2007, Bazrgari et al., 2008, Bazrgari et al., 2009, Arjmand et al., 2010). In this model, muscle forces are estimated such that equilibrium equations are satisfied across the entire lumbar spine. The finite element model included a sagittally symmetric thorax-pelvis model of the spine composed of six non-linear flexible beam elements and six rigid elements (Figure 1) (Arjmand and Shirazi-Adl, 2005, Bazrgari et al., 2008). The six rigid elements represented the thorax, and each of lumbar vertebrae from L1 to L5, while the six flexible beam elements characterized the nonlinear stiffness of each intervertebral disc between the T12 and S1 vertebrae. Intervertebral discs' stiffness were defined using nonlinear axial compression–strain relationships along with moment–rotation relationships in sagittal/coronal/transverse planes that were obtained from earlier numerical and experimental studies of lumbar spine motion segments (Yamamoto et al., 1989, Oxland et al., 1992, Shirazi-Adl et al., 2002). Upper-body mass and mass moments of inertia were distributed along the spine according to reported ratios (Zatsiorsky and Seluyanov, 1983, De Leva, 1996, Pearsall et al., 1996). Inter-segmental damping with properties defined based on earlier experimental studies were also considered using connector elements (Markolf, 1970, Kasra et al., 1992). The muscle architecture in the biomechanical model included 56 muscles (Fig. 1); 46 muscles connecting lumbar vertebrae to the pelvis (i.e., local muscles) and 10 muscles connecting thoracic spine/rib cage to the pelvis (i.e., global muscles) (Arjmand and Shirazi-Adl, 2005, Arjmand and Shirazi-Adl, 2006, Bazrgari et al., 2008, Bazrgari et al., 2008).

Figure 1 may be inserted here

To determine the required muscle forces for satisfaction of equilibrium across the entire lumbar spine, segmental kinematics in the lumbar region were required. Since only kinematics of the thorax and the pelvis were available from the experimental measurements, a heuristic optimization procedure (Figure 2) was used in the biomechanical model to determine a set of segmental kinematics in the lumbar region (i.e., from L1 to L5) such that the corresponding set of predicted muscles forces minimized a cost function (Shojaei and Bazrgari, 2014). The cost function used for this heuristic optimization procedure was the sum of squared muscle stress across all lower back muscles. Specifically, a set of possible segmental kinematics in the lumbar region that was within the reported range of motion of lumbar motion segments was initially prescribed on the FE model and the equations of motion were solved using an implicit integration algorithm inside an FE software (ABAQUS, Version 6.13, Dassault Systemes Simulia, Providence, RI). The outputs of equations of motion were three-dimensional moments at each spinal level, from T12 to L5, that were to be balanced by muscles attached to these same spinal levels. Because the number of attached muscles to these levels (i.e., 10 muscles in each level from T12 to the L4 and 6 muscles at L5) was more than the number of equilibrium equations (i.e., three at each vertebra), a local optimization problem was also solved for each level to obtain a set of muscle forces that minimize the aforementioned cost function only at that specific level (Arjmand and Shirazi-Adl, 2006). These local optimization procedures were performed using the Lagrange Multiplier Method. The above procedure was repeated inside the heuristic optimization for as many possible sets of segmental kinematics, determined using a genetic algorithm, until a set of segmental kinematics was obtained that meets the optimization criterion. The associated muscle forces with the optimal local kinematics were then used to estimate spinal loads at all lumbar levels. These spinal loads included compression forces, along with anterior-posterior and medio-lateral components of the shear forces, relative to the mid-plane of the intervertebral disc and at each lumbar level. The heuristic optimization procedure was developed in Matlab (The MathWorks Inc., Natick, MA, USA, version 7.13).

Figure 2 may be inserted here

2.3 Statistical analyses: Rather than comparing the predicted forces in all 56 muscles between the two groups, the summation of forces in global and local muscles were separately used for statistical analyses. Similarly, rather than comparing spinal loads at each level, levels with highest spinal loads (i.e., L4-L5 or L5-S1 for compression forces and L5-S1 for shear forces) were considered for subsequent statistical analyses. For each outcome measure, local maxima were extracted from the stance phase of each leg, resulting in the following values: 1) two peaks in the predicted global and local muscle forces (Fig. 3; Peak-1 at heel strike of the ipsilateral limb and Peak-2 at toe off the contralateral limb), 2) two peaks in the predicted compression forces (Fig. 4; Peak-1 at heel strike of the ipsilateral limb and Peak-2 at toe off the contralateral limb), and 3) one peak in each of the lateral (Fig. 5; at toe off of the contralateral limb), anterior (Fig. 5; at toe off of the contralateral limb), and posterior shear forces (Fig. 5; at heel strike of the ipsilateral limb). It is of note that the gait cycle was defined from right heel strike to subsequent right heel strike for controls, and from heel strike of the intact leg to next heel strike of the intact leg for persons with LLA. Prior to statistical analyses, all maxima were normalized with respect to total body mass. Furthermore, because there was no significant differences ($P>0.21$ from paired t-tests) in any of the aforementioned maxima between the right and left legs of controls, statistical analyses were performed using the mean values for the two legs of control group.

3. RESULTS

Mean sum of global and local muscle forces for both groups are depicted in Figure 3. Mean sum of maximum global muscle forces was 2.6 N/kg larger at heel strike of the intact vs. prosthetic limb among persons with LLA (Table 2); the sum of global muscle forces was only significantly larger at intact heel strike in persons with LLA than the corresponding value in controls. For local muscles at the instant of heel strike, there were no significant differences ($P>0.41$) within and between groups. At toe-off, the mean sum of maximum global muscle forces was 3.6 N/kg larger in intact vs. prosthetic limb stance among persons with LLA; this local maximum was also 5.6 N/kg larger in intact stance among persons with LLA than controls, but not significantly different between prosthetic stance relative to controls. For local muscles at the instant of toe-off, while there were no significant differences between the values in the stance phase of intact and prosthetic legs of persons with LLA, they were, respectively, 2.5 N/kg and 1.5 N/kg larger than the corresponding values in controls.

Figure 3 may be inserted here

Table-2 may be inserted here

Mean compression forces were 3.4 N/kg larger at heel strike of the intact vs. prosthetic leg among persons with LLA; the compression force at heel strike of the intact leg was also 4.8 N/kg larger than the corresponding value in controls, while there were no significant differences between the prosthetic leg of persons with LLA and the corresponding value in controls (Table 2). Mean compression force at toe off of the contralateral limb was similar between stance of the intact and prosthetic legs among persons with LLA, but were 8.6 N/kg (4.7 N/kg) larger during intact (prosthetic) leg stance than the corresponding value in controls.

Figure 4 may be inserted here

In the lateral direction, maximum shear forces were 4.3 N/kg larger in the stance phase of the intact vs. prosthetic leg among persons with LLA (Table 2). These were also 3.3 N/kg larger in the stance phase of intact leg of persons with LLA than the corresponding value in controls; there were no significant differences between the stance phase of prosthetic leg and that of controls. In the posterior direction, maximum shear forces among controls were 1.3 and 1.8 N/kg larger than the corresponding values in intact and prosthetic stance among persons with LLA, respectively. Maximum posterior shear forces were not different between intact and prosthetic stance among persons with LLA. In the anterior direction, maximum shear forces were 1.4 N/kg larger in the stance phase of the intact vs. prosthetic leg among persons with LLA; these were also 1.8 N/kg larger in the stance phase of the intact leg than the corresponding value in controls.

Figure 5 may be inserted here

4. DISCUSSION

In this study, trunk muscle responses to walking demands and the resultant spinal loads were estimated in individuals with and without unilateral LLA. It was hypothesized that individuals with LLA would require larger muscle forces to overcome the physical demands of walking while maintaining spinal equilibrium and stability, which would in turn result in larger spinal loads compared to individuals without amputation. The results obtained through computational simulations and subsequent statistical analyses confirmed our hypothesis. Higher trunk muscle forces and larger spinal loads on the lower back of individuals with unilateral LLA during walking may be in part responsible for the reported higher prevalence of LBP among persons with vs. without LLA.

The local maxima for muscle forces and the resultant spinal loads occurred at the instants of heel strike and toe off within the gait cycle. These time points also happen to correspond with the instances of large axial twist of the trunk (i.e., heel strike) and asymmetric trunk posture (i.e. toe off where there were relatively large motions in all three planes (Hendershot and Wolf, 2014)). In addition to individual muscle responses, co-activations of antagonistic muscles were needed under such trunk motions to assure spine equilibrium in three-dimensional space. The effects of such an increased and asymmetric motion on muscle forces is more evident when comparing the kinematics and associated muscle forces in the stance phase of intact and prosthetic legs among individuals with LLA. The increases in trunk motion and its asymmetry at instances of heel strike and toe off were more pronounced during the stance phase of the intact leg of persons with LLA, particularly at heel strike of the ipsilateral limb (Hendershot and Wolf, 2014), that resulted in much larger muscle forces during the stance phase of intact than prosthetic leg. Such an effect may also be a result of proximal compensations (e.g., hip-hiking) to assist with toe clearance (Michaud et al., 2000), or simply because these individuals feel more confident during intact (vs. prosthetic) stance to advance their center of mass.

The sum of forces in global muscles during the gait cycle was comparable with the sum of forces in the local muscles (Fig. 3). It should be mentioned, however, global muscles were the primary responders to activity demands during the first iteration of muscle force calculations in our model (i.e., the local loop in Fig. 2). As the effects of such global muscle forces were applied into the model, during the subsequent iterations, local muscles became activated to prevent buckling of the spine under the penalties of global muscle forces. If the summation of forces in global and local muscles is assumed to represent the required energy for respectively equilibrate and stabilize the spine, our results suggest that relatively equal amounts of energy were consumed to provide equilibrium and stability to the spine during walking. However with such an assumption, it seems that overcoming the equilibrium demands of walking impact the spinal loads of individuals with LLA more than overcoming its segmental stability demands when compared with able-bodied individuals. This observation is reflected in the sum of differences in mean global muscle forces (i.e., assumed to represent differences in equilibrium demands) between persons with and without LLA that was 955 N larger than the sum of differences in mean local muscle forces (i.e., assumed to represent differences in stability demands) between the same two groups. We should, however, emphasize that such interpretation is limited to assumptions made in our optimization-based method for estimation of muscle responses to activity demand and would require verification via measurement of muscle activity. A stabilizing response from local muscles as suggested here should occur sooner than equilibrating response from global muscles.

The predicted spinal loads for controls were in agreement (in terms of patterns and magnitudes) with those obtained in earlier studies (Cappozzo, 1983, Khoo et al., 1995, Cheng et al., 1998, Callaghan et al., 1999, Yoder et al., 2015). Depending on walking speed, the reported values of maximum compression force at the lower spinal level ranged between 1.0 to 2.95 times body weight for walking speeds ranging from 0.9 to 2.2 m/s (Table 3). The mean maximum compression force from these studies, along with average walking speed, were respectively ~ 1.94 times body weight at 1.4 m/s, which are comparable with our predictions of a maximum spinal load of ~ 1.85 times body weight for an average walking speed of ~1.35 m/s. Maxima in predicted compression forces in this study occurred around heel strike and toe off instances within the gait cycle, which are also consistent with reported timing of maximum compression forces in earlier studies: around toe off instants (Callaghan et al., 1999), within a short time interval around toe off (Cappozzo, 1983), right after the heel strike and before complete toe off (Cheng et al., 1998), and around 20% and 80% of walking cycle (Khoo et al., 1995).

Table-3 may be inserted here

The results obtained from individuals with unilateral LLA in this study were also consistent in pattern and magnitude with those reported by Cappozzo and Gazzani (Cappozzo and Gazzani, 1982). This earlier study reported spinal loads for two subjects (i.e., one with transfemoral amputation and one with knee ankylosis) during level-ground walking. The reported maxima of predicted compression forces for the person with LLA) ranged from 2 to 3 times body weight for walking speeds between 1.0 m/s and 1.5 m/s (Table 3), which is consistent with the range of maxima of predicted compression forces in this study (~ 2 to 2.6 body weight). In both studies, the maximum compression forces occurred during intact limb stance at the instance of prosthetic toe off. In a more recent study (Yoder et al 2015), much smaller maxima (i.e., ~ body weight) have been reported for maximum spinal loads among persons with transtibial LLA; though smaller maxima could be due, in part, to the relatively slower walking speed and/or more distal amputation.

The sample of persons with LLA in this study included young and physically fit members of the military with transfemoral amputations resulting from traumatic injuries. Thus, the results cannot be generalized to groups with other levels or etiologies of amputation. This cross sectional study also does not provide any information about lower back biomechanics in these individuals before the amputations, and history of LBP was not controlled in the participants, though those with current LBP were excluded from the study. Although we accounted for individual differences in trunk inertial properties in the non-linear FE model of spine, we used the same passive tissue properties for all subjects since we had no access to the subject-specific behavior of such tissues (i.e., ligaments, intervertebral discs, passive behavior of muscles and bony structures) for these participants. Furthermore, same heights were considered in the spine model for all subjects, though stature was not significantly different between groups.

5. CONCLUSION

Asymmetric and larger trunk motion of individuals with LLA during walking requires higher activation and co-activation of trunk muscles to assure equilibrium and stability of the spine, which in turn increase spinal loads. An elevated level of spinal loads during a basic activity of daily living like walking may increase risk of developing LBP, in particular due to the repetitive nature of such activity. It is imperative to investigate whether those with LLA consistently experiencing higher levels of spinal loads during other important activities of daily living (e.g., ascending and descending ramps or stairs) as a result of an alteration in internal tissue responses to activity demands. Such knowledge can inform future development of effective clinical programs aimed at reducing the risk for developing LBP via management of spinal loads during daily activities.

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TABLE AND FIGURE CAPTIONS

Table-1: Participant characteristics for the control (CTL) and lower limb amputation (LLA) groups. (Hendershot and Wolf, 2014).

Table-2: Mean (SD) predicted maximum muscle forces and resultant spinal loads.

Table-3: Reported values of maximum compression force (*body weight) at the lower spinal level.

Figure 1. Sagittal view of the biomechanical model including FE model of the spine and 56 trunk muscles (dimensions in mm). ICPL: iliocostalislumborum pars lumborum, ICPT: iliocostalislumbroum pars thoracis, IP: iliopsoas, LGPL: longissimusthoracis pars lumborum, LGPT: longissimusthoracis pars thoracis, MF: multifidus, QL: quadratuslumborum, IO: internal oblique, EO: external oblique and RA: rectus abdominus.

Figure 2. The process used to estimate muscle forces and spinal loads. Each set of possible segmental kinematics is generated using a genetic algorithm subjected to measured kinematics of thorax and pelvis as well as the reported values of lumbar segments' range of motion. The convergence in the local and global loops are achieved when the changes in respectively sum of predicted muscle forces in two consecutive local iterations and the value of the cost function of the heuristic optimization procedure in two consecutive global iterations are less than 1%.

Figure 3. Mean sum of forces in global (i.e., muscles attached to the thoracic spine – top) and local (i.e., muscles attached to the lumbar spine – bottom) muscles. CTL: control group, LLA: group with lower limb amputation.

Figure 4. Mean compression forces at mid-plane of the L4-L5 (top) and L5-S1 (bottom) intervertebral discs. CTL: control group, LLA: group with lower limb amputation.

Figure 5. Mean shear forces at the mid-plane of the L5-S1 in lateral (top) and antero-posterior (bottom) directions. CTL: control group, LLA: group with lower limb amputation. Positive shear force in lateral direction indicates force toward the right (intact) leg for controls (LLA) and positive shear force in antero-posterior direction indicate anterior direction.

Table-1: Participant characteristics for the control (CTL) and lower limb amputation (LLA) groups. (Hendershot and Wolf, 2014).

Variable	CTL (n=20)	LLA (n=20)
Age (year)	28.1 (4.8)	29.20 (6.70)
Stature (cm)	181.00 (6.10)	176.20 (6.70)
Body mass (kg)	83.90 (8.60)	80.60 (12.20)

Table-2: Mean (SD) predicted maximum muscle forces and resultant spinal loads.

Variable	Control (n=20)	Transfemoral Amputation (n=20)	
		Intact Stance	Prosthetic Stance
MUSCLE FORCES			
Global (thorax) – Peak 1 (N/kg)	7.7 (2.5)	10.4 (5.0) *	7.8 (3.0) †
Global (thorax) – Peak 2 (N/kg)	7.0 (2.6)	12.6 (5.2) *	9.0 (4.1) †
Local (lumbar) – Peak 1 (N/kg)	8.4 (2.0)	8.9 (2.1)	8.1 (1.7)
Local (lumbar) – Peak 2 (N/kg)	7.8 (1.4)	10.3 (3.1) *	9.3 (2.3) *
SPINAL LOADS			
Compression – Peak 1 (N/kg)	18.2 (3.4)	23.0 (5.8) *	19.6 (4.1) †
Compression – Peak 2 (N/kg)	16.8 (3.3)	25.4 (7.0) *	21.5 (4.8) *
Lateral Shear (N/kg)	5.5 (1.1)	8.8 (1.6) *†	4.5 (1.2)
Posterior Shear (N/kg)	3.7 (0.8)	2.4 (0.8) *	1.9 (0.6) *
Anterior Shear (N/kg)	4.2 (1.0)	6.0 (1.1) *	4.6 (0.9) †

* Significant difference relative to control

† Significant difference between intact vs. prosthetic

Table-3: Reported values of maximum compression force (*body weight) at the lower spinal level.

Study		Walking Speed (m/s)						
		0.90	1.00	1.20	1.35	1.50	1.70	2.20
Typical walking	Current study				1.85			
	Cappozzo, 1983		1.20		1.50		1.90	2.50
	Cheng et al., 1998		2.28	2.53		2.95		
	Khoo et al., 1995			1.71				
	Yoder et al., 2015	1.0						
Atypical walking	Current study				2.60			
	(Cappozzo and Gazzani, 1982) (amputation)		2.00		2.70	3.00		
	(Cappozzo and Gazzani, 1982) (knee ankylosis)		1.80			2.10		
	Yoder et al., 2015	1.0						

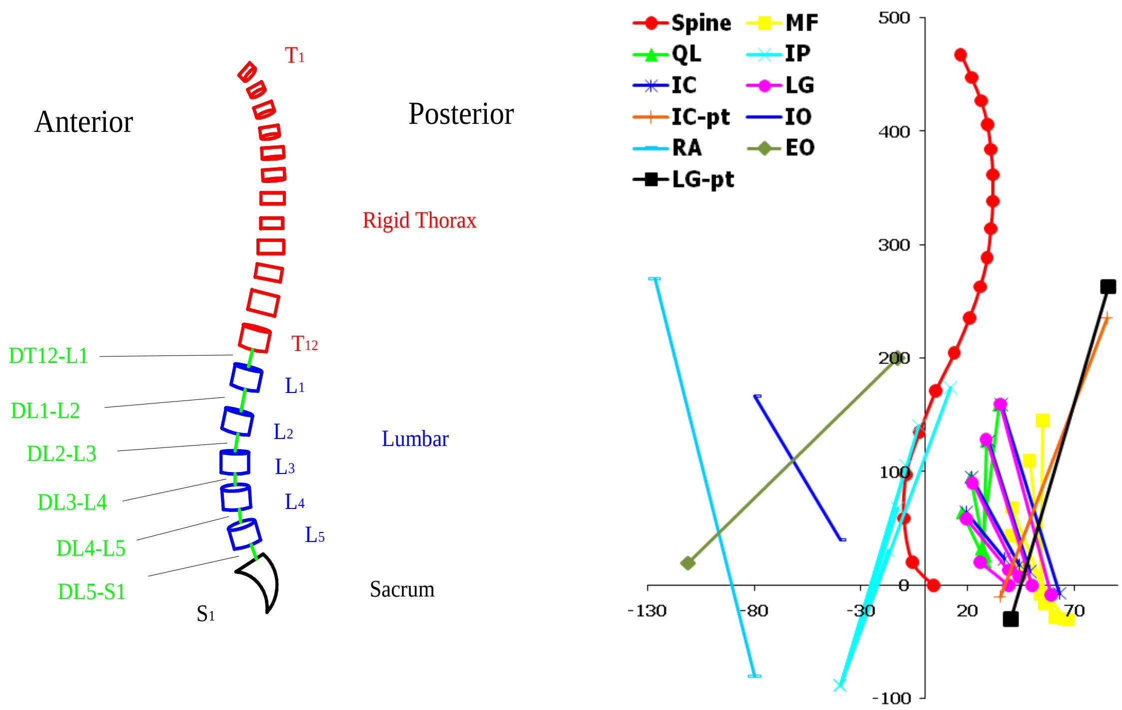

Figure 1. Sagittal view of the biomechanical model including FE model of the spine and 56 trunk muscles (dimensions in mm). ICPL: iliocostalislumborum pars lumborum, ICPT: iliocostalislumbroum pars thoracis, IP: iliopsoas, LGPL: longissimusthoracis pars lumborum, LGPT: longissimusthoracis pars thoracis, MF: multifidus, QL: quadratuslumborum, IO: internal oblique, EO: external oblique and RA: rectus abdominus.

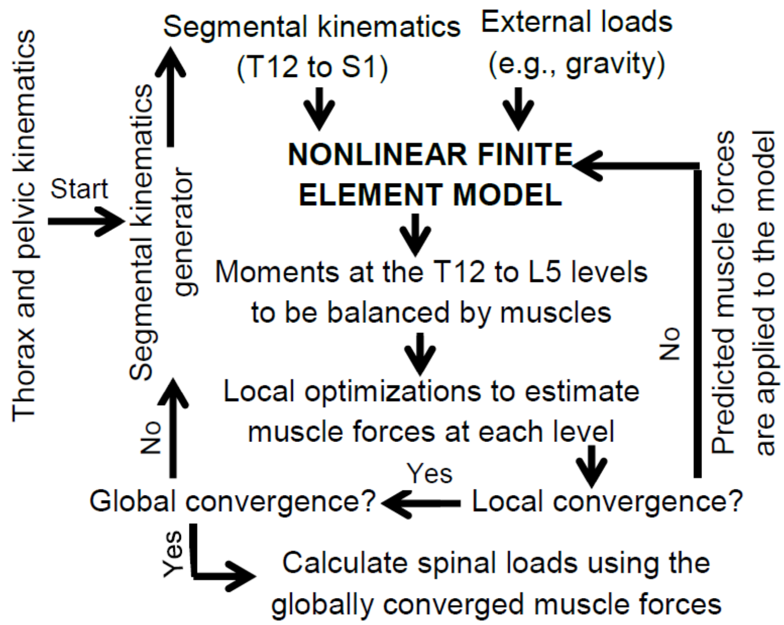

Figure 2. The process used to estimate muscle forces and spinal loads. Each set of possible segmental kinematics is generated using a genetic algorithm subjected to measured kinematics of thorax and pelvis as well as the reported values of lumbar segments' range of motion. The convergence in the local and global loops are achieved when the changes in respectively sum of predicted muscle forces in two consecutive local iterations and the value of the cost function of the heuristic optimization procedure in two consecutive global iterations are less than 1%.

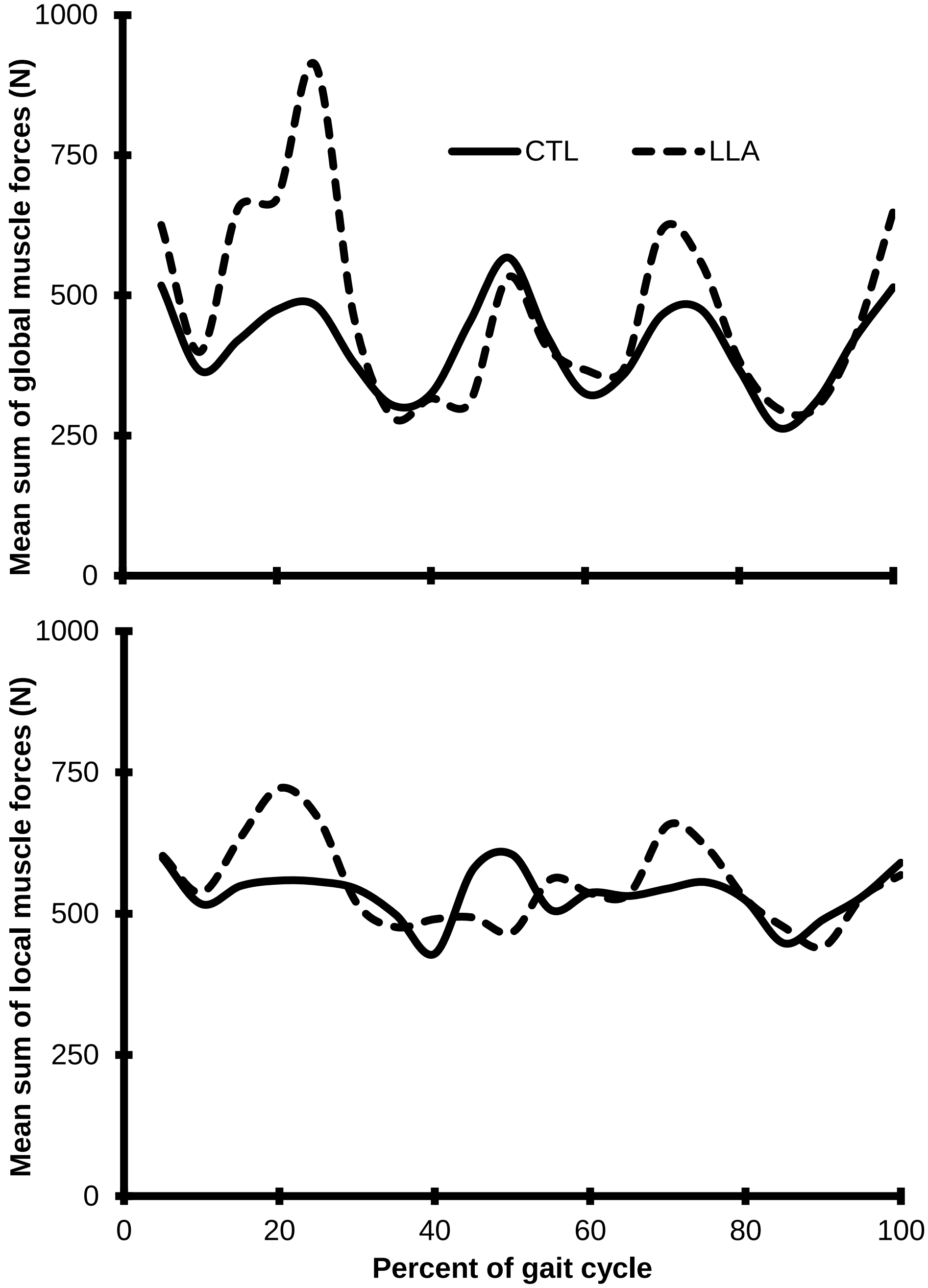

Figure 3. Mean sum of forces in global (i.e., muscles attached to the thoracic spine – top) and local (i.e., muscles attached to the lumbar spine – bottom) muscles. CTL: control group, LLA: group with lower limb amputation.

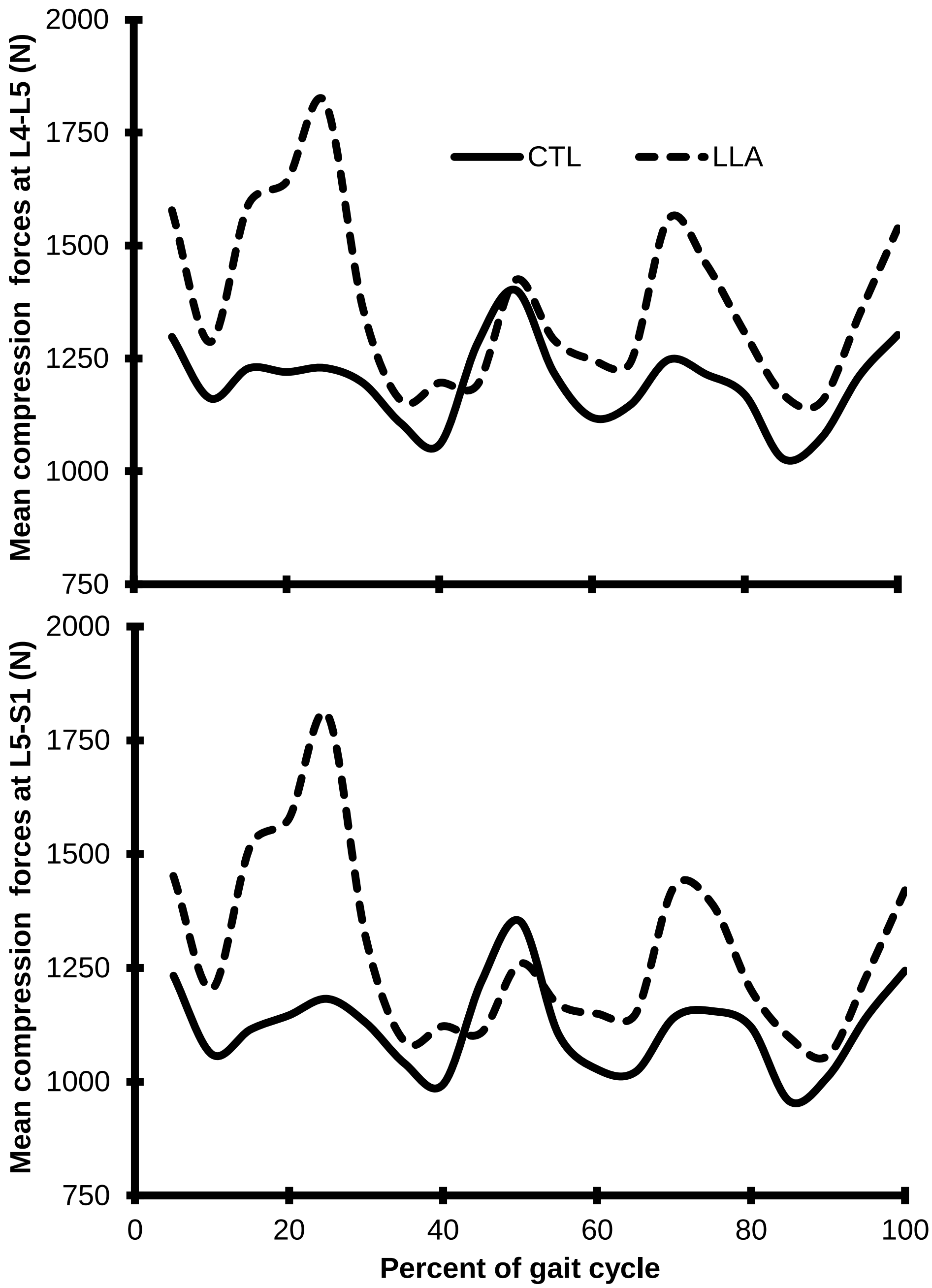

Figure 4. Mean compression forces at mid-plane of the L4-L5 (top) and L5-S1 (bottom) intervertebral discs. CTL: control group, LLA: group with lower limb amputation.

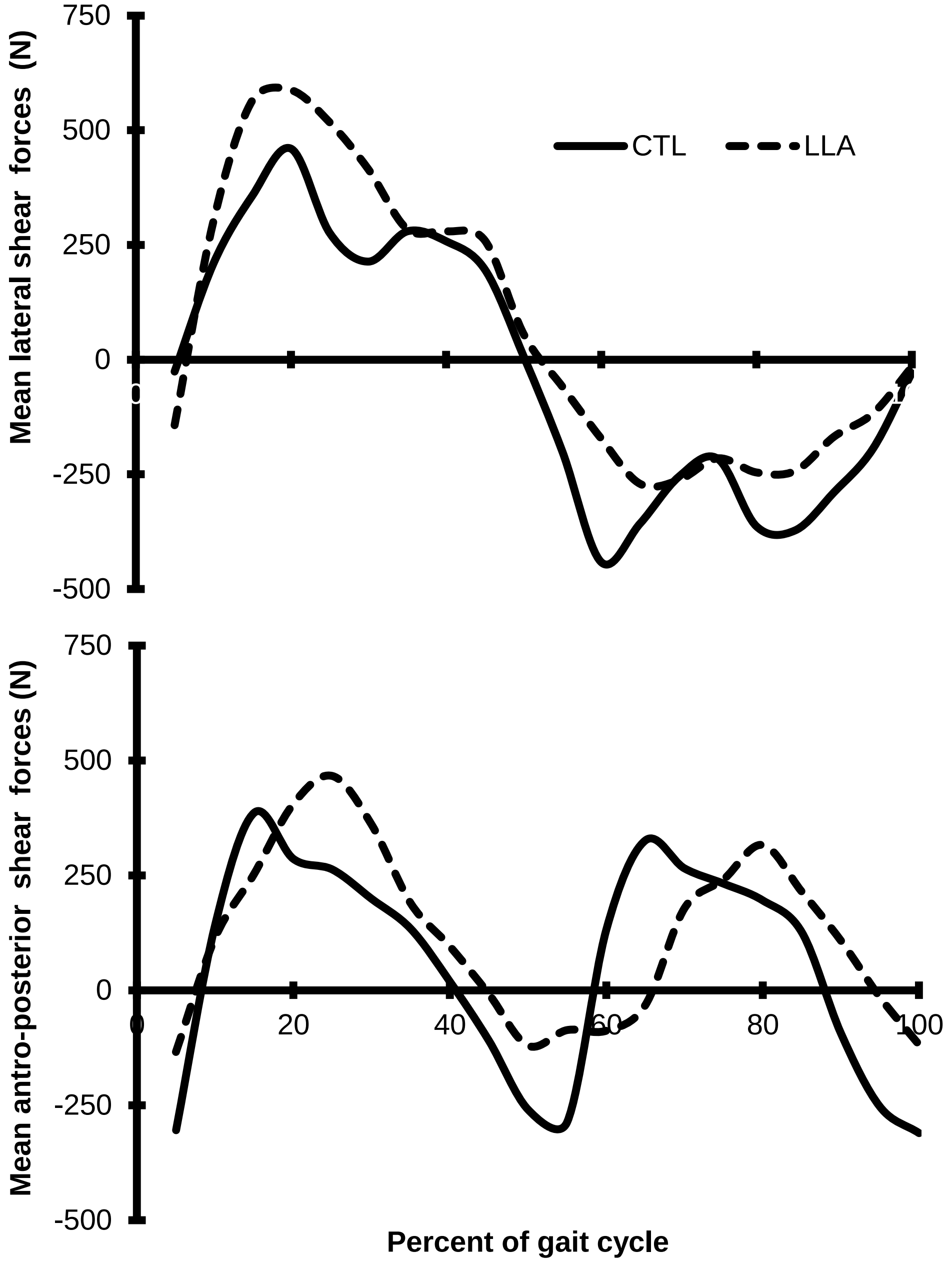

Figure 5. Mean shear forces at the mid-plane of the L5-S1 intervertebral disc in lateral (top) and antero-posterior (bottom) directions. CTL: control group, LLA: group with lower limb amputation. Positive shear force in lateral direction indicates force toward the right (intact) leg for controls (LLA) and positive shear force in antero-posterior direction indicate anterior direction.

Changes in Gait following Transfemoral Amputation Increase Spinal Loads

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Persons with transfemoral amputation (TFA) report a considerably higher prevalence of low back pain (LBP) compared to able-bodied individuals. Altered gait mechanics with TFA, particularly increased and asymmetric trunk motion, likely impose distinct demands on trunk muscles to maintain stability and equilibrium of the spine. Since alterations in trunk kinematics and muscle responses influence spinal loads, and spine loads are linked with LBP risk, the goal of this work was to demonstrate the effects of increased and asymmetric trunk kinematics with TFA on the relative contributions of external (i.e., gravity and inertia) and internal (i.e., muscle) forces to spine loads. Peak lumbar (i.e., thorax with respect to pelvis) lateral bending and forward lean obtained during gait from 20 persons with TFA (and 20 without), at 10 (4)° and 6 (3)°, respectively, were input into a kinematics-driven finite element model of the spine [1]. Total compressive and shear forces at the L5-S1 disc were computed, as well as relative contributions of internal and external forces. Influences of lumbar posture and mechanical properties of the passive ligamentous spine were also investigated.

Total compressive and shear forces at the L5-S1 disc were substantially larger among persons with (vs. without) TFA, at 1548 (785) and 429 (252) N, respectively. Given the comparable contributions from external forces between groups (≈ 350 N in compression and 150 N in shear), the main cause for such higher spinal loads is the internal muscle response to spinal equilibrium requirements; muscle force contributions among persons with (vs. without) TFA were 1201 (434) N in compression and 299 (114) N in shear. Additional simulations with altered lumbar postures and passive tissues properties among persons with TFA revealed minimal changes in spinal loads (<150 N), but again with larger contributions from muscle forces. Although obtained from static simulations (i.e., no inertia), these results clearly support our hypothesis of abnormal spine loading with altered trunk motion in persons with TFA, who here, exhibited substantially larger spinal loads compared to able-bodied controls. Due to the cyclic nature of gait, repeated exposures to increased spinal loads may accelerate degenerative changes in the spine and/or increase the risk for chronic LBP.

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References

[1] Bazrgari B., et al. J Biomech 2008; 41: 412-421.